REMARKS

The applicant has studied the Office Action dated October 23, 2000, and has made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-72 are pending, claims 1, 11, 35, 38, and 39 have been amended, and claims 56-72 have been added. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-55 were rejected under 35 U.S.C. § 102(b) as being anticipated by Vasko 5,573,506. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an external infusion device for infusion of a liquid into a body of a user. The external infusion device may be worn under clothing, and may include an RF programming capability, a carbohydrate (or bolus) estimation capability, and/or vibration alarm capability, either alone or in combination. The disclosure of the Vasko reference and the structure of the Vasko pump unit and homebase prohibit a reading of the Vasko reference onto the embodiments recited in the claims. Therefore, prior to a specific discussion of the differences between the Vasko reference and the claims, the applicants will discuss the general structure of the Vasko device.

The Vasko reference is directed to an intravenous infusion system for use in a home. The system includes a pump unit 12 and a homebase 14. The pump unit 12 includes a housing 16 that encloses the electronic and mechanical components of the pump unit 12, such as a display 20 and controls 22 (see col. 4, lines 54-61). The homebase 14 also includes a cradle 24 for holding the pump unit 12, a cable 50 for providing power to the pump unit 12, controls 26 for controlling the operation of the homebase 14 only, display lights 28, and an audio device 29 for providing an alarm (see col. 4, lines 62-67).

In addition, the homebase 14 includes a local modem communication port 42 and a remote modem communication port 44 for wired communication with a modem-based programmer (see col. 5, lines 3-8). The controls 26 of the homebase 14 are used to access a local or remote programmer through the ports 42 or 44 (see col. 4, lines 64-65; col. 5, lines 1-2; col. 8, lines 9-54) . The homebase 14 is not itself a pump programmer, and thus the controls 26 are incapable of being used to program the pump unit 12.

In the Vasko reference, the pump unit 12 can communicate with the homebase 14 through wireless IR ports 46 and 48. However, it is important to note that the homebase 14 cannot be used without a local or a remote modem-based programmer that is wire connected to either port 42 or 44 of the homebase 14, so that the homebase 14 can relay program information to the pump unit 12 (see col. 5, lines 49-53). Without the pass-through by the homebase 14, the pump unit 12 cannot be remotely programmed. Thus, the homebase 14 is merely a relay unit for the remote modem-based programmer device (such as a telephone or DTMF device) that is directly wired into modem port 42 or 44. The pump unit 12 and homebase 14 may be integrated into a single unit to obviate the need for the data ports 46 and 48. In this case, ports 46 and 48 would be omitted and a telephone data line or DTMF device would be plugged into port 42 or 44 through a wired connection (see col. 4, lines 48-53 and col. 5, lines 9-28 and 49-63). Thus, there is no disclosure, teaching, or suggestion of using a remote wireless connection to ports 42 or 44, and therefore there is no disclosure, teaching, or suggestion of using a remote wireless programmer to communicate with the pump unit 12. The structurally bulky layout of the Vasko device and the fundamental operational scheme taught by the Vasko reference, prohibit the claims from reading on the Vasko reference, as will now be discussed in more detail below.

CLAIMS 1-10:

The Examiner has cited no portion of the Vasko reference that teaches or suggests the embodiments as recited in claims 1-10. Claim 1, for example, has been amended to recite, "...an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion

device is capable of being concealed from view on an individual when being remotely commanded," (emphasis added). As discussed in the detailed description of the application, the external infusion pump is portable and allows for concealment of the external infusion device under clothes, in pouches, or the like (see page 12, lines 21-23). The Examiner has cited no portion of the Vasko device, which teaches or suggests an external infusion device, "capable of being concealed from view on an individual when being remotely commanded," as recited in claim 1. In fact, as discussed above, the Vasko device can only be remotely commanded through wire connections or phone lines using modem ports 42 or 44. Also, the Vasko device includes at least one bulky homebase 14, which is a stationary system, that sits on a counter top, as shown in Fig. 1. Thus, wired communication during programming would not permit the Vasko device to be worn on an individual and concealed from view on the individual, since the wires would be in view during programming. Also, the Vasko device teaches away from concealment on an individual, since it uses IR ports 46 and 48 that would likely be interfered with if concealed. Furthermore, the disclosed size of the Vasko device is too large to conceal on an individual.

Dependent claim 3 is further distinguished from the Vasko reference by reciting, "...wherein the external infusion device includes a memory for storing a patient infusion history and pump activity," (emphasis added). The Vasko reference does not disclose, teach, or suggest a memory for storing a patient infusion history, as recited in claim 3. The Vasko device has three types of memory: a protocol memory 51, a voice storage unit 52, and an access code memory 54. The protocol memory 51 contains information about the pump unit's 12 present settings and the volume of fluid infused during the present administration to the patient (see col. 12, line 11 through col. 13, line 23). The voice storage unit 52 contains digitized voice signals for use with a voice synthesizer 49 (see col. 6, lines 26-29). And the access code memory 54 stores access codes (see col. 7, lines 49-63). None of the memories included in the Vasko device store patient infusion history, as recited in claim 3.

Claim 4 is further distinguished from the Vasko reference by reciting, "wherein the remotely generated commands are capable of programming and activating an audio bolus

delivery of the liquid by the external infusion device," (emphasis added). The Examiner has cited no portion of the Vasko reference that discloses, teaches, or suggests a device where the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, as recited in claim 4. The Vasko device does include an internal audio device 29 for providing audio alarm signals. However, the only use for the audio device 29 is to operate in response to various alarm conditions (col. 4, lines 66-67, and col.16, line 60 through col. 17 line 19). There is no teaching or suggestion in the Vasko reference of the audio device 29 being used in conjunction with the administration of a bolus, as recited in the claim 4.

Claim 5 is further distinguished from the Vasko reference by reciting, "... the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device," (emphasis added). The Examiner has failed to cite any portion of the Vasko reference that discloses, teaches, or suggests a vibration bolus. The Vasko reference contains no description of a vibration device. Furthermore, the Vasko reference does not teach or suggest the use of a vibration device in conjunction with a bolus delivery, as recited in the claim5.

Claim 9 is further distinguished from the Vasko reference by reciting, "... the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device," (emphasis added). The Examiner has cited no portion of the Vasko reference that discloses, teaches, or suggests a dual wave bolus delivery of liquid. A care provider may program the Vasko device to deliver fluid in one of five ways: 1) Continuous mode, which delivers a specified volume of fluid at a continuous specified rate; 2) Intermittent Mode, which delivers fluid at a background rate and intermittently delivers equal doses of fluid at a specified rate, volume per dose, total number of doses, and time between doses; 3) Taper Mode, which delivers a specified volume of fluid over a specified time, but tapers up and then tapers down the delivery rate during the delivery time; 4) PCA Mode (ml), which delivers a specified volume of fluid at a continuous rate and allows the patient to request

boluses of fluid of which the size, interval, and number per hour are limited by the care provider; and 5) PCA Mode (mgs) , which is similar to the PCA Mode (ml) but specifies doses in weight rather than volume (see Figs. 8(a, b and c) and col. 14, line 53 through col. 15, line 62). The Vasko reference does not disclose and actually teaches away from a dual wave bolus fluid delivery by offering modes of delivery that do not allow for the creation of a dual wave.

Accordingly, it is respectfully submitted that claims 1-10 are not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIMS 11-34:

Claim 11 has been amended to recite, "An infusion system for infusing a liquid into a body, the infusion system comprising: an external infusion device including: a housing, a receiver coupled to the housing and for receiving remotely generated commands, a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands, and an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed when being remotely commanded; and a remote commander including: a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device," (emphasis added). As described in the detailed description of the application, the transmitter may utilize RF frequencies, optical, infrared (IR), ultrasonic frequencies, magnetic effects, or the like to communicate with the external infusion device. The Examiner has cited no portion of the Vasko reference that in any manner teaches or suggests the embodiments as recited in claims 11-34. For example, the Vasko reference does not disclose, teach, or suggest an infusion system including an external infusion device and a remote commander, the external infusion device including a receiver for receiving remotely generated commands, and the remote commander including a transmitter for wirelessly transmitting commands to the receiver of the external infusion device, as recited in claim 11.

As discussed above, the homebase 14 is not a remote commander. The homebase 14 cannot be used to remotely generate commands. The control buttons 26 on the homebase 14 are only used to select between wire modem communication ports 42 or 44 for sending or receiving wired communications with another programmer. The Vasko reference does not disclose that the control buttons 26 can be used to program the pump unit 12, or that they have any other functional capability, other than selecting between wire modem communication ports 42 or 44 and initiating an information download to a computer.

The Vasko device teaches away from other usage of the control buttons 26, since the intent is to make interaction with the homebase 14 simple. For instance, the Vasko device uses voice assisted programming to simplify the programming method (see col. 6, lines 18-62). The homebase 14 receives all remotely generated commands and signals for programming the pump unit 12 through one of the two wired communication ports, either the remote communication port 42 or the local communication port 44. Signals for programming the pump unit 12 are generated remotely by a telephone or another similar device, and are carried to the homebase 14 by wire. The Vasko device includes a pump unit 12 with an IR emitter/detector 46 and a homebase 14 with an IR emitter/detector 48 to permit wireless communication between the two (see cols.5 and 6). However, these are not used by the homebase 14 to program the pump 12, since the homebase 14 is not a remote programmer. In addition, there is no disclosure to teach or suggest the remote programmer can even interface with the ports 46 and 48. The Vasko reference states that the emitter/detectors 46 and 48 may be hard wired together, or the pump unit and the homebase 14 may comprise a single unit obviating the need for a link between the two units (col. 5 lines 54-59). However, all remote commands to program the pump unit 12 are still sent through a wire from a device (remote programmer) other than the homebase 14, through the homebase 14 to the pump unit 12. Thus, the Vasko reference does not teach or suggest a remote commander including a transmitter for wirelessly transmitting commands to the receiver of the external infusion device, as recited in claim 11.

Claim 12 is further distinguished by reciting, "wherein the external infusion device further includes a device transmitter to verify receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device," (emphasis added). The Vasko device does not include a remote commander with a receiver to receive the verification from the device transmitter of the external infusion device. The Examiner rejected claim 12 stating that a remote receiver is implied by the disclosure of a wait light 36. However, the wait light 36 of the Vasko reference is located on the homebase 14. The wait light 36 indicates when the homebase 14 is involved in a programming session or when it is downloading a protocol to a remote computer. But, as discussed previously, the homebase 14 is not a remote commander. Furthermore, the remote commander does not have a remote receiver to receive verification from the wait light 36. Thus, the Vasko reference does not teach or suggest the additional features of an external infusion device that includes a device transmitter to verify receipt of commands from the remote commander, and a remote commander that includes a remote receiver to receive the verification from the device transmitter of the external infusion device, as recited in claim 12.

Claim 13 is further distinguished from the Vasko reference by reciting, "wherein the remote commander is sized to fit on a key ring." The Examiner has failed to cite any portion of the Vasko reference that includes the additional feature that a remote commander is sized to fit on a key ring, as recited in claim 13.

The Examiner rejected claims 14-20, stating that the Vasko reference discloses an infrared emitter/detector and other wireless communications ports. Claims 14 –17, and 19 recite, "wherein the remote commander uses," RF frequencies, IR (infrared) frequencies, optical frequencies, ultrasonic frequencies, or magnetic effects, "to transmit remote commands to the external infusion device," (emphasis added). As discussed above, all wireless communication described in the Vasko reference are between the pump unit 12 and the homebase 14. And since

the homebase 14 is not a remote commander, the Vasko reference does not disclose, teach, or suggest a remote commander that uses a form of wireless communication, as recited in the claims. According to the Vasko reference, all communications from a remote commander are though a wire to local or remote communication ports 42 or 44 on the homebase 14. Thus, the Vasko reference does not teach or suggest the additional feature of a remote commander that uses a form of wireless communication, as recited in claims 14-20.

The Examiner rejected claims 21-22 stating that the Vasko reference discloses infrared emitter/detectors and other wireless communications, and that an identification code to avoid interference with other devices is implied. The Vasko device uses infrared emitter/detectors and/or other wireless communication devices to communicate between the pump unit 12 and the homebase 14, which are connected by a power cord 50, which implies that the distance between the two devices is significantly limited and changes of interface are likely small. Thus, the Vasko reference does not teach or show a need for an identification code to avoid interference with other devices, since it is connected to the pump unit 12 and the homebase 14. Furthermore, the Vasko device is stationery and designed to sit on a counter top for use in a home. Thus, there is generally little concern with regard to a homebase communicating with a pump unit that is associated with a different homebase. Finally, the Vasko reference does not disclose, teach, or suggest the additional feature of an identification code to prevent interference in any of its embodiments.

Claim 21 recites, "wherein the processor of the external infusion device has a unique identification code, and wherein the remote commander includes the capability to read and learn the unique identification code of the external infusion device, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices," (emphasis added), and claim 22 similarly recites, "wherein the remote commander has a unique identification code, and wherein the processor of the external infusion device includes the capability to read and learn the unique identification code of the remote commander, and wherein the remote commander and the

external infusion device use the unique identification code to substantially avoid interference with other remote commanders," (emphasis added). The Examiner has cited no portion of the Vasko reference that discloses, teaches, or suggests an external infusion device that has a unique identification code that can be read by a remote commander, or a remote commander that has a unique identification code that can be read by an external infusion device, as recited in the claims. The Vasko device uses access codes entered by a person in order to gain access to the programming protocol. The access codes are intended to protect against unwanted programming of the pump protocol (see col. 7, lines 26-48, cols. 9-11, and Figs. 3 and 4). But, the access codes are not disclosed as providing protection against interference, as recited in claims 21 and 22.

Claims 26 and 27 are further distinguished over the Vasko reference by reciting, "wherein the remote commander is capable of receiving data from another medical device and relaying the received data to the external infusion device," and furthermore, "the remote commander is capable of remotely commanding and controlling the other medical device." The Examiner has cited no portion of the Vasko reference, which teaches or suggests a remote commander capable of receiving data from another medical device and relaying the data to the external infusion device, as recited in claim 26. Nor has the Examiner cited a portion of the Vasko reference, which further teaches or suggests a remote commander that could also remotely command and control the other medical device, as recited in the claims. The Vasko reference discloses that the Vasko pump/homebase system may be used for wired controlling and programming of an infusion pump, and that a variety of pump applications exist. Also, other medical applications exist in which the system may be adapted for wired remote programming including use with, "ventilators (e.g. blood/oxygen level), respiratory equipment, EKG machines, blood gas analyzers, enteral pumps (i.e. stomach infusion pumps), blood glucose monitors, dialysis equipment, open wound irrigation devices, and urology equipment" (see col. 17, lines 32-47). However, in all cases, the Vasko device is used to program only one device. The Vasko reference does not teach or suggest the additional feature of a device that is capable of programming an external infusion pump and also communicating with, and/or commanding and

controlling another device, as recited in claims 26 and 27.

Claims 28 and 29 are further distinguished over the Vasko reference by reciting, "wherein the remote commander is capable of programming and activating an audio bolus delivery of the liquid by the external infusion device," and "wherein the remote commander is capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device," (emphasis added). As discussed with respect to claims 4 and 5 above, the Examiner has cited no portion of the Vasko reference that discloses, teaches, or suggests a remote commander that is capable of programming and activating an audio bolus or a vibration bolus delivery of the liquid by the external infusion device, as recited in claims 28 and 29.

Accordingly, it is respectfully submitted that claims 11-34 are not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIMS 35-43:

The Examiner rejected claims 35-43, stating, "a bolus estimator, a liquid sensitivity, infusion of insulin, and carbohydrate intake, are disclosed, or at least implied, in column 17, lines 37 and 44-45." As pointed out by the Examiner, in col. 17, the Vasko reference suggests that the Vasko device may be used in several infusion applications including an insulin pump, and that the Vasko invention may be used for remote programming of one of several medical devices including blood/gas analyzers and blood glucose monitors. However, the applicants respectfully submit that no portion of the Vasko reference discloses, teaches, or implies a bolus estimator, a liquid sensitivity, or a carbohydrate intake, as recited in claims 35-43.

The Examiner has cited no portion of the Vasko reference that in any manner teaches or suggests the embodiments recited in claims 35-43. For example, claim 35 has been amended to recite, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and an indication

device to indicate when an amount of fluid to be infused has been calculated," (emphasis added). The Vasko reference does not disclose, teach, or suggest an external infusion device that includes a bolus estimator used to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body. The Vasko device requires the care provider to enter the volume of fluid to be delivered, as shown in Figs. 6(A and B), and 8(A and B), and does not discuss or suggest anything related to ingested material. In fact, the Vasko reference teaches away from a bolus estimator to estimate an amount of liquid to be infused, since all embodiments of the Vasko device require that all bolus amounts be entered by a care provider (see cols.13-16). Thus, the Vasko reference does not disclose, teach, or suggest a bolus estimator using an estimate of ingested material, as recited in claim 35.

Dependent claims 36, 37, and 40 are further distinguished from the Vasko reference by reciting specific additional features of the bolus estimator that are not disclosed, taught, or suggested in the Vasko reference. The Examiner has cited, no portion of the Vasko reference that teaches or suggests an external infusion device with a bolus estimator that includes, "the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value," as recited in claim 36, or "a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus," as recited in claim 37, or "a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus is estimated by the bolus estimator," as recited in claim 40.

Claims 38 and 39 have been amended to recite that the material is ingested, and are further distinguished over the Vasko reference by reciting, "the liquid to be infused is insulin," and "where the material to be ingested is carbohydrates," respectively. While the Vasko invention may be used for insulin pumps, there is no teaching or suggestion in the Vasko reference of the additional feature of a device to estimate an amount of insulin to be infused based upon an estimate of carbohydrates to be ingested by the body, as recited in claims 38 and 39.

Claims 41 and 42 are further distinguished over the Vasko reference by reciting that the supplied values used in conjunction with the a bolus estimator and the processor are, "codes representing a carbohydrate value of specific foods," or "codes representing a carbohydrate value of specific meals," respectively. The Vasko reference does not teach or suggest the additional feature of a device with a bolus estimator that accepts codes representing a carbohydrate value of foods or meals, as recited in claims 41 and 42.

Claim 43 is further distinguished over the Vasko reference by reciting that the external infusion device further includes, "a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused," (emphasis added). The Vasko reference actually teaches away from an external infusion device with any capability to calculate a value that adjusts the amount of fluid to be infused, by describing in detail how the care provider must enter the amount and rate of fluid to be infused for all of the delivery modes, as shown in Figs. 6(A and B), and 8(A and B). Thus, the Examiner has cited no portion of the Vasko reference that teaches or suggests the additional feature of a duration factor to adjust the amount of the fluid to be infused.

Accordingly, it is respectfully submitted that claims 35-43 are not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIMS 44-50:

The Examiner rejected claims 44-52 (believed to be 50 since 51 and 52 do not recite a vibration alarm) stating that a vibration alarm is disclosed at 500 and 29, which may include a variety of alarm functions, including low battery alarm, a low volume alarm, etc. (see column 16, lines 44-57). The applicants respectfully submit that the Vasko reference does not disclose, teach, or suggest the use of a vibration alarm. The Examiner has cited an alarm table 500 in the Vasko reference. However, this is merely a list of alarm functions, as shown in Fig. 10, and not a description of alarm generating mechanisms. Alarm functions, as described in the Vasko

reference, are detectable events such as "air in line," "bad battery," "bar code fault," and more (see in col. 16 lines 43-53), that are used to trigger an alarm. Therefore, these alarm functions are reasons to start an alarm, and are not different mechanisms of providing notification. According to the Vasko reference, the only methods of providing alarm notification are the use of either the alarm light 40 or the audio device 29. The alarms may be audible or visual (see col. 16, lines 53 to col. 17, line 18). But, there is no teaching or suggestion of providing as an alarm indication or notification by a vibration alarm as recited in claims 44-50.

Claims 44-50 are further distinguished over the Vasko reference by claiming unique applications or uses for the vibration alarm. Claims 44-46 state that the vibration alarm is used to, "remove gas bubbles from the fluid in the reservoir during priming," "agitate fluid in the reservoir between successive delivery periods," or "agitate the fluid in the reservoir during delivery," respectively. Claims 48 and 49 recite similar language. Claim 47 recites, " a vibration alarm used in conjunction with the processor and the audible alarm." And claim 50 recites that, "the processor selects to activate one of the audible alarm and vibration alarm independently." The Vasko reference does not disclose, teach, or suggest uses for a vibration alarm alone, or in conjunction with an audible alarm, as recited in claims 44-50.

Accordingly, it is respectfully submitted that claims 44-50 are not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIM 51:

Claim 51 recites, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a keypad coupled to the housing and used in conjunction with the processor to determine an estimate of remaining battery power, and an indication device to indicate the estimate of remaining battery power," (emphasis added). The Vasko reference does not disclose teach or suggest the use of a keypad coupled to the housing of the infusion device to determine an estimate of remaining battery power. The Vasko reference discloses alarm functions for "bad batteries," "change

batteries," and " low batteries," and the use of the audio device 29 or alarm light 40 to become activated when an alarm is triggered (see Fig. 10). However, in the Vasko device, the alarms are disclosed as being sounded automatically without the use of a keypad. Furthermore, the Vasko reference does not teach or suggest a device to estimate the remaining battery power, nor does it teach or suggest an indication device to indicate the estimate of the remaining battery power, as recited in claim 51.

Accordingly, it is respectfully submitted that claim 51 is not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIMS 52 and 53:

Claims 52 and 53 recite, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, ...a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns, ... an indication device to indicate the selected personal delivery pattern, wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns," (emphasis added). The Vasko reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. The Vasko device does offer various delivery modes for providing a protocol to operate the pump unit 12 including a continuous mode, an intermittent mode, a taper mode, a PCA ml mode, and a PCA mg mode. Each mode operates the pump unit 12 in a different fashion. For example, the PCA modes are used to allow the user to request at-will bolus doses that are limited in size and number by the care provider. And the taper mode is used to keep a vein open. However, modes are modes-of-operation, and are not personal delivery patterns, as recited in the claims. To change the operation of the pump unit 12, a care provider must first select a mode, then enter or verify various parameters associated with the mode, and finally select to send the new protocol to the pump unit 12, as shown in Figs. 6(A) - 9. Only one set of parameters is stored and sent to the pump unit 12. Parameters that were used previously but are not the current parameters for a mode are not available in the memory. So, for example, if the care provider

would like to continue to use the same delivery mode such as the intermittent mode or a PCA mode, but needs to change the parameters used by the mode back to previously used parameters, the care provider would have to re-enter the previously used parameters before sending them to the pump unit 12. The Vasko device does not provide a memory for storing and accessing previously used parameters. Thus, values for only one set of parameters are stored for each mode, and the Vasko reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in claims 52 and 53.

Accordingly, it is respectfully submitted that claims 52 and 53 are not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIM 54:

Claim 54 recites, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising:...a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles, a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles, and an indication device to indicate the basal rate profiles during programming, wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles," (emphasis added). The Vasko reference does not disclose, teach, or suggest an external infusion device including a memory to store at least two basal rate profiles, as recited in the claim. As discussed above, the Vasko reference does not teach a memory to store at least two delivery patterns. Furthermore, although the Vasko reference discloses a continuous mode, it does not allow for creation of a profile since it only allows one delivery rate. Still further, the Vasko reference teaches that only the current protocol (rather than at least two basal profiles) is stored for the pump unit 12 to use.

Accordingly, it is respectfully submitted that claim 54 is not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CLAIM 55:

Claim 55 recites, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a memory coupled to and used in conjunction with the processor to store at least two bolus types, a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two bolus types, and an indication device to indicate the selected bolus type, wherein the processor controls the external infusion device in accordance with the selected one of the at least two bolus types," (emphasis added). As discussed above, none of the delivery modes of the Vasko device allow for more than one set of parameters to be entered and stored in the memory. The Vasko reference does not disclose, teach, or suggest an external infusion device including a memory to store at least two bolus types, as recited in the claim.

Accordingly, it is respectfully submitted that claim 55 is not anticipated under 35 U.S.C. § 102(b) by the Vasko reference.

CONCLUSION OF CLAIM REJECTIONS

Therefore, it is respectfully submitted that the rejection of claims 1-55 under 35 U.S.C. § 102(b) should be withdrawn.

NEW CLAIMS 56-72

Claims 56-72 have been added by this amendment. No new matter has been added. It is respectfully submitted that claims 56-72 are in condition for allowance.

Claim 56 is further distinguished by reciting, "an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device, wherein the indication device produces an audible indication," (emphasis added). The Vasko reference does not disclose, teach, or suggest an infusion device with an indication device that that produces an audible indication that a command has been received or to indicate when a command is being used to control the external infusion device.

The only audio device disclosed in the Vasko reference is an internal audio device 29 used specifically to sound an alarm in response to the alarm functions listed on the alarm table 500 (see Fig. 10, and col. 16, line 43 through col. 17, line 19). The Vasko reference does not teach or show that the internal audio device 29 is used to indicate that the command has been received or that command is being used by the external infusion device. Therefore, claim 56 does not read on the Vasko reference, and the applicants respectfully submitted that claim 56 is in condition for allowance.

Claim 57 is further distinguished by reciting, "an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device, wherein the indication device produces a vibratory indication," (emphasis added). The Vasko reference does not disclose, teach, or suggest an infusion device with an indication device that produces a vibratory indication that a command has been received or to indicate when a command is being used to control the external infusion device. In fact, the Vasko reference does not teach or suggest the use of a vibratory indication for any purpose. Furthermore, the Vasko reference does not discuss the use of any device to indicate when a command has been received or when the command is being used to control the external infusion device. Therefore, the applicants respectfully submit that claim 57 does not read on the Vasko reference and is in condition for allowance.

Claim 58 is further distinguished by reciting an infusion system comprising, "a remote commander including...a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device, wherein the remote commander is portable," (emphasis added). The Vasko reference does not disclose, teach, or suggest an infusion system with a remote commander that has a transmitter for wirelessly transmitting commands to the receiver of the external infusion device, and where the remote commander is portable. As discussed above, the homebase 14 of the Vasko device receives commands by wire through modem ports 42 and 44, and then transfers those commands to the pump unit 12. The Vasko reference does not disclose or suggest a portable device for wirelessly transmitting

commands to a receiver of the pump unit 12. The pump unit 12 of the Vasko reference only receives commands from the homebase 14. The homebase 14 is bulky and designed to fit on a countertop (see Fig. 1). The homebase 14 includes modem ports 42 and 44 for connecting to phone lines, which suggests that the homebase 14 is tethered to a wall by a phone line. The Vasko reference does not teach or suggest that the homebase 14 is portable. Therefore, the applicants respectfully submitted that claim 58 does not read on the Vasko reference and is in condition for allowance.

Claim 59 is further distinguished by reciting an infusion system comprising a remote commander, "wherein the remote commander is one or more remote commanders and each of the one or more remote commanders includes: a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device," (emphasis added). The Vasko device receives commands by wire through either a local modem port 44 or a remote modem port 42. The local modem port 44 is for a local telephone at the premises. A care provider presses a local button 32 to activate the local modem port 44 to communicate with the homebase 14 (see calm 5, lines 15 to 25). Thus, the local modem port 44 is not used for a remote commander. Only the remote port modem 42 receives remote commands, and those are received by wire. The Vasko reference does not teach or suggest one or more remote commanders for wirelessly transmitting commands to the receiver of the external infusion device, as recited in claim 59. Therefore, the applicants respectfully submitted that claim 59 does not read on the Vasko reference and is in condition for allowance.

Claim 60 is further distinguished by reciting, "wherein the one or more remote commanders each have a unique identification code, and wherein the processor of the external infusion device includes the capability to store the unique identification codes of the one or more remote commanders, and wherein the one or more remote commanders and the external infusion device use the unique identification codes to substantially avoid interference with other remote commanders," (emphasis added). The Vasko reference does not disclose, teach, or suggest the

use of remote commanders each with a unique identification code that the external infusion device stores and uses to substantially avoid interference with other remote commanders. The unique identification codes for each of the one or more remote commanders are not to be confused with the access codes described in the Vasko reference. The access codes are typed into a telephone by a care provider to gain access to information or protocols stored in the homebase 14 (see Fig. 4, and col. 10, line 37 through col. 11, line 50). The access codes are used as a security precaution and not to identify a remote commander. The Vasko reference does not teach or suggest that access codes may be used in any way to avoid interference with other remote commanders, and furthermore, the access codes of the Vasko reference are not unique to individual remote commanders, as recited in claim 60. Therefore, the applicants respectfully submit that claim 60 does not read on the Vasko reference and is in condition for allowance.

Claim 61 is further distinguished by reciting, "wherein the external infusion device is programmable to store one or more identification codes, wherein each remote commander transmits an identification code, and wherein the external infusion device only responds to commands sent from a remote commander that transmits an identification code that has been programmed into the external infusion device," (emphasis added). The Vasko reference does not disclose, teach, or suggest an external infusion device that is programmable to store one or more identification codes and will only respond to commands sent from a remote commander that transmits an identification code that has been programmed. The pump unit 12 of the Vasko device receives commands only from the homebase 14, which, as discussed previously, is not a remote commander. And, the homebase 14 only transmits protocol to the pump unit 12. It does not transmit identification codes. Furthermore, the Vasko reference does not teach or suggest the use of identification codes. As discussed previously, the Vasko reference employs access codes typed into a telephone to obtain access to the homebase 14. Therefore, the applicants respectfully submit that claim 61 does not read on the Vasko reference and is in condition for allowance.

Claim 62 is further distinguished by reciting, "wherein the remote commander establishes

non-line of sight communication with the external infusion device." The Vasko reference does not disclose, teach, or suggest a remote commander that establishes non-line of sight communication with the external infusion device. The Vasko device has a homebase 14 that communicates with the pump unit 12 using line of sight infrared communication ports 46 and 48, or the homebase 14 and the pump unit 12 may be combined as one unit (see col. 5, lines 49 through 56). The Vasko reference also teaches a telephone used to communicate with the homebase 14. But the Vasko reference does not teach or suggest a remote commander that commander establishes non-line of sight communication with the external infusion device, as recited in claim 62. Therefore, the applicants respectfully submit that claim 62 does not read on the Vasko reference and is in condition for allowance.

Claim 63 is further distinguished by reciting an external infusion device including a receiver for receiving remotely generated commands, "wherein the receiver includes a standby mode, and wherein while the receiver is in the standby mode the receiver does not receive." The Vasko reference does not disclose, teach, or suggest an external infusion device with a receiver that does not receive while in a standby mode. The Vasko device includes the pump unit 12 with an infrared emitter/detector port 46 for receiving wireless communication from the homebase 14. The Vasko reference does not teach or suggest that the infrared port 46 has a standby mode during which it would not receive information from the homebase 14. Therefore, the applicants respectfully submit that claim 63 does not read on the Vasko reference and is in condition for allowance.

Claim 64 is further distinguished by reciting, an external infusion device including a receiver for receiving remotely generated commands, ...wherein while the receiver is in the standby mode the receiver does not receive and, "wherein the receiver periodically becomes active to see if the transmitter is transmitting," (emphasis added.). The Vasko reference does not disclose, teach, or suggest an external infusion device with a receiver that periodically becomes active to see if a transmitter is transmitting. The Vasko device includes the pump unit 12 with an infrared emitter/detector port 46 for receiving wireless communication from the emitter/detector

port 48 on the homebase 14. The Vasko reference does not teach or suggest that the infrared port 46 periodically becomes active to receive information from the homebase 14. Therefore, the applicants respectfully submit that claim 64 does not read on the Vasko reference and is in condition for allowance.

Claim 65 is distinguished from the Vasko reference by reciting, "An external infusion device for infusion of a liquid into a body of a user, the external infusion device comprising: a housing containing a reservoir, a processor coupled to the housing, and a vibration alarm used in conjunction with the processor to provide one or more tactile sensations to a user," (emphasis added). The Vasko reference does not disclose, teach, or suggest a vibration alarm to provide tactile sensations to a user. The Vasko device includes an audio alarm 29 and an alarm light 40 to respond to alarm functions shown in an alarm table 500 (see Figs. 1 and 10, and col. 16, line 53 through col. 17 line 19). However, the Vasko reference does not teach or suggest the use of a vibration alarm. Therefore, the applicants respectfully submit that claim 65 does not read on the Vasko reference and is in condition for allowance.

Claims 66-69 are distinguished over the Vasko reference by virtue of including a vibration alarm as discussed above, and serve to further describe embodiments of the present invention. The applicants respectfully submit that claims 66-69 do not read on the Vasko reference and are in condition for allowance.

Claim 70 is further distinguished by reciting an external infusion device including a processor to store at least two personal delivery patterns..., "wherein the at least two personal delivery patterns are programmable by a user," (emphasis added). As discussed previously, the Vasko reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. Furthermore, the Vasko reference does not disclose, teach, or suggest at least two personal delivery patterns are programmable by a user. The protocol for the pump unit 12 is programmed by a care provider. The Vasko reference teaches away from user programming since the care provider must enter an access code to gain access to the homebase

14 to change the protocol (see col. 9, lines 39-54). In fact, in some modes the care provider enters parameters that set limits on the maximum size of a dose and the dose frequency to prevent the user from requesting too much medication (see Figs. 6 (A) and (B), and col. 13, line 24 through col. 14, line 10). Therefore, the applicants respectfully submit that claim 70 does not read on the Vasko reference and is in condition for allowance.

Claims 71 and 72 are distinguished over the Vasko reference by virtue of arguments presented earlier that the Vasko reference does not teach or suggest the use of two or more personal delivery patterns. Claims 71 and 72 serve to further define embodiments of the present invention. The applicants respectfully submit that claims 71 and 72 do not read on the Vasko reference and are in condition for allowance.

Accordingly, it is respectfully submitted that all of the new claims 56-72 are allowable.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5493 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

Dated: 4/5/01

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1. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a receiver coupled to the housing for receiving remotely generated commands;

a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands; and

an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded.

2. An external infusion device according to claim 1, wherein the external infusion device includes a memory for storing programs, and wherein the receiver is capable of receiving software updates and facilitating remote programming of external infusion device capabilities.

3. An external infusion device according to claim 1, wherein the external infusion device includes a memory for storing a patient infusion history and pump activity.

4. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device.

5. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device.

6. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device.

7. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device.

8. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device.

9. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device.

10. An external infusion device according to claim 1, wherein the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device.

11. An infusion system for infusing a liquid into a body, the infusion system comprising:

an external infusion device including:

a housing;

a receiver coupled to the housing and for receiving remotely generated commands;

a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands; and

an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed when being remotely commanded; and

a remote commander including:

a commander housing;

a keypad coupled to the commander housing for inputting commands; and

a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device.

12. An infusion system according to claim 11, wherein the external infusion device further includes a device transmitter to verify receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device.

13. An infusion system according to claim 11, wherein the remote commander is sized to fit on a key ring.

14. An infusion system according to claim 11, wherein the remote commander uses RF frequencies to transmit remote commands to the external infusion device.

15. An infusion system according to claim 11, wherein the remote commander uses IR frequencies to transmit remote commands to the external infusion device.

16. An infusion system according to claim 11, wherein the remote commander uses optical frequencies to transmit remote commands to the external infusion device.

17. An infusion system according to claim 11, wherein the remote commander uses ultrasonic frequencies to transmit remote commands to the external infusion device.

18. An infusion system according to claim 11, wherein the remote commander uses audio frequencies to transmit remote commands to the external infusion device.

19. An infusion system according to claim 11, wherein the remote commander uses magnetic effects to transmit remote commands to the external infusion device.

20. An infusion system according to claim 11, wherein the remote commander is capable of providing remote commands at a distance greater than 1 inch.

21. An infusion system according to claim 11, wherein the processor of the external infusion device has a unique identification code, and wherein the remote commander includes the capability to read and learn the unique identification code of the external infusion device, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices.

22. An infusion system according to claim 11, wherein the remote commander has a unique identification code, and wherein the processor of the external infusion device includes the capability to read and learn the unique identification code of the remote commander, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other remote commanders.

23. An infusion system according to claim 11, wherein the remote commander includes a mode that permits physician controlled programming of specific capabilities of the external infusion device to the exclusion of the user.

24. An infusion system according to claim 11, wherein the remote commander may also include a link to a computer to allow computer programming to initiate or alter available capabilities of the external infusion device.

25. An infusion system according to claim 11, wherein the external infusion device includes a memory for storing programs, and wherein the receiver is capable of receiving software updates to facilitate remote programming of external infusion device capabilities.

26. An infusion system according to claim 11, wherein the remote commander is capable of receiving data from another medical device and relaying the received data to the external infusion device.

27. An infusion system according to claim 26, wherein the remote commander is capable of remotely commanding and controlling the other medical device.

28. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating an audio bolus delivery of the liquid by the external infusion device.

29. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device.

30. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device.

31. An infusion system according to claim 11, wherein the remote commander is capable of programming and suspending delivery of the liquid by the external infusion device.

32. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating an extended bolus delivery of the liquid by the external infusion device.

33. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device.

34. An infusion system according to claim 11, wherein the remote commander is capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device.

35. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a processor coupled to the housing;

a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and

an indication device to indicate when an amount of fluid to be infused has been calculated.

36 An external infusion device according to claim 35, wherein the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value.

37. An external infusion device according to claim 36, wherein the bolus estimator includes a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus.

38. An external infusion device according to claim 37, wherein the liquid to be infused is insulin, and where the material to be ingested is carbohydrates.

39. An external infusion device according to claim 35, wherein the liquid to be infused is insulin, and where the material to be ingested is carbohydrates.

40. An external infusion device according to claim 35, wherein the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator.

41. An external infusion device according to claim 35, wherein the supplied values are codes representing a carbohydrate value of specific foods.

42. An external infusion device according to claim 35, wherein the supplied values are codes representing a carbohydrate value of specific meals.

43. An external infusion device according to claim 35, further including a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused.

44. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing containing a reservoir;

a processor coupled to the housing; and

a vibration alarm used in conjunction with the processor to provide an alarm, and to generate sufficient vibration to assist in removing gas bubbles from the fluid in the reservoir during priming of the external infusion device.

45. An external infusion device according to claim 44, wherein the vibration alarm is used to agitate the fluid in the reservoir in between successive delivery periods of the fluid by the external infusion device.

46. An external infusion device according to claim 44, wherein the vibration alarm is used to agitate the fluid in the reservoir during delivery of the fluid by the external infusion device.

47. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing containing a reservoir;

a processor coupled to the housing;

an audible alarm coupled to the processor; and

a vibration alarm used in conjunction with the processor and the audible alarm to provide an alarm.

48. An external infusion device according to claim 47, wherein the vibration alarm is also used to agitate the fluid in the reservoir in between successive delivery periods of the fluid by the external infusion device.

49. An external infusion device according to claim 47, wherein the vibration alarm is also used to agitate the fluid in the reservoir during delivery of the fluid by the external infusion device.

50. An external infusion device according to claim 47, wherein the processor selects to activate one of the audible alarm and vibration alarm independently of the unselected alarm.

51. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a processor coupled to the housing;

a keypad coupled to the housing and used in conjunction with the processor to determine an estimate of remaining battery power; and

an indication device to indicate the estimate of remaining battery power.

52. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns;

a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two personal delivery patterns; and

an indication device to indicate the selected personal delivery pattern,

wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns.

53. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a receiver coupled to the housing for receiving remotely generated commands;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns, wherein the processor is coupled to the receiver to receive the remotely generated commands and to control the external infusion device in accordance with the commands to select one of the at least two personal delivery patterns; and

an indication device to indicate the selected personal delivery pattern and when a command has been received to control the external infusion device in accordance with the selected personal delivery pattern such that the external infusion device is capable of being concealed from view when being remotely commanded,

wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns.

54. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles;

a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles; and

an indication device to indicate the basal rate profiles during programming,

wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles.

55. An external infusion device for infusion of a liquid into a body, the external infusion device comprising:

a housing;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two bolus types;

a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two bolus types; and

an indication device to indicate the selected bolus type,

wherein the processor controls the external infusion device in accordance with the selected one of the at least two bolus types.

56. An external infusion device according to claim 1, wherein the indication device produces an audible indication.

57. An external infusion device according to claim 1, wherein the indication device produces a vibratory indication.

58. An external infusion device according to claim 11, wherein the remote commander is portable.

59. An infusion system according to claim 11, wherein the remote commander is one or more remote commanders and each of the one or more remote commanders includes:

a commander housing;

a keypad coupled to the commander housing for inputting commands; and

a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device.

60. An infusion system according to claim 59, wherein the one or more remote commanders each have a unique identification code, and wherein the processor of the external infusion device includes the capability to store the unique identification codes of the one or more remote commanders, and wherein the one or more remote commanders and the external infusion device use the unique identification codes to substantially avoid interference with other remote commanders.

61. An infusion system according to claim 11, wherein the external infusion device is programmable to store one or more identification codes, wherein each remote commander transmits an identification code, and wherein the external infusion device only responds to commands sent from a remote commander that transmits an identification code that has been programmed into the external infusion device.

62. An infusion system according to claim 11, wherein the remote commander establishes non-line of sight communication with the external infusion device.

63. An infusion system according to claim 11, wherein the receiver includes a standby mode, and wherein while the receiver is in the standby mode the receiver does not receive.

64. An infusion system according to claim 63, wherein the receiver periodically becomes active to see if the transmitter is transmitting.

65. An external infusion device for infusion of a liquid into a body of a user, the external infusion device comprising:

a housing containing a reservoir;

a processor coupled to the housing; and

a vibration alarm used in conjunction with the processor to provide one or more tactile sensations to a user.

66. An external infusion device according to claim 65, wherein the vibration alarm provides one or more tactile sensations to the user in response to a low reservoir alert.

67. An external infusion device according to claim 65, wherein the vibration alarm provides one or more tactile sensations to the user in response to a communication from a remote commander.

68. An external infusion device according to claim 65, wherein the vibration alarm provides one or more tactile sensations to the user in response to one or more commands to change one or more operations of the external infusion device.

69. An external infusion device according to claim 65, wherein the vibration alarm provides one or more tactile sensations to the user during a period that the infusion device is in a suspend mode.

70. An external infusion device according to claim 52, wherein the at least two personal delivery patterns are programmable by a user.

71. An external infusion device according to claim 52, wherein the keypad is used to program the at least two personal delivery patterns.

72. An external infusion device according to claim 52, wherein the selected one of the at least two personal delivery patterns repeats daily.